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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,475

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Dirk Inze

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23117 7590 11/23/2009
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,475	Applicant(s) INZE ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,10,13,14,40,43,44,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 10, 13-14, 40, 43-44 and 47-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>72409,71309</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1638

DETAILED ACTION

Applicant's submission filed on July 13, 2009 has been entered.

Claims 2-3, 5-9, 11-12, 15-39, 41-42, 45-46 and 49-50 are cancelled.

Claims 1 and 40 are currently amended.

Claims 1, 4, 10, 13-14, 40, 43-44 and 47-48 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 10, 13, 40, 43-44 and 47 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record.

Applicant's arguments filed July 13, 2009 have been fully considered but they are not persuasive.

Applicants maintain that one of ordinary skill in the art will be able to introduce and to express a specific nucleic acid in a plant cell without undue experimentation, and that the

Art Unit: 1638

specification further describes such methods. Applicants also point to a description of experiments carried out by the applicants or under the control or direction of the applicants as evidence of enablement. (reply pages 4-7)

Applicant's arguments are not persuasive because it is the unpredictability of the effect of introducing and expressing a specific nucleic acid in a plant cell that is the basis of the rejection. Applicant's arguments are also not persuasive because any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under 37 CFR § 1.132

Applicants additionally maintain that reliance on Temple is misplaced and that one of ordinary skill in the art cannot compare the results obtained by Temple with the subject matter of the claims, because expression of a nucleic acid and down-regulation of a nucleic acid are two distinct approaches. Applicants further maintain that Temple is not instructive of the level of skill in the art at the time of the present application because of its publication date. (reply pages 8-9).

Applicant's arguments are not persuasive, as the outstanding rejection does not equate the method of Temple and the claimed method, and does not assert that Temple is instructive of the level of skill in the art at the time of the present application. The outstanding rejection asserts that plants having modified levels or activities of a protein are not always predictably obtainable, since conditions that modify gene expression do not always modify the level or activity of the protein encoded by the gene. Temple is properly exemplary support for this assertion, which is independent of the method employed, and does not depend on the level of skill in the art.

Art Unit: 1638

Applicants also maintain that they understand the Examiner to believe that Sakamoto would teach that the native expression of AZF2 (SEQ ID NO:1835) could be induced by various stresses. However, *Arabidopsis* plants transgenic for the AZF2 coding sequence under the control of the CaMV 35S promoter over-expressing AZF2 could not be obtained. (reply page 9)

Applicant's arguments are not persuasive. The outstanding rejection clearly acknowledges that *Arabidopsis* plants transgenic for the AZF2 coding sequence under the control of the CaMV 35S promoter over-expressing AZF2 could not be obtained. See page 5 of the office action mailed March 12, 2009. Accordingly, Sakamoto is properly exemplary support for the assertion that plants transgenic for a sequence that is natively expressed are not always predictably obtainable, since native and recombinant expression conditions may not be equivalent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 as currently amended is indefinite in the recitation of “and/or modifying level,”. It is unclear what level is modified, since the amendment to the claim removed all language to this effect. It is suggested that the phrase be deleted from the claim in order to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 48 remain rejected under 35 U.S.C. 102(b) as being anticipated by De Veylder L. et al. (Control of proliferation, endoreduplication and differentiation by the *Arabidopsis* E2Fa-DPa transcription factor. EMBO J. 2002 Mar 15;21(6):1360-8), for the reasons of record.

Applicant's arguments filed July 13, 2009 have been fully considered but they are not persuasive.

Applicants submit that de Veylder et al. does not disclose introducing and expressing a polynucleotide having a sequence of the claims into a plant or a plant cell, as claimed, and that a polynucleotide as shown in SEQ ID NO:1835 is not over-expressed in plants transgenic for *Arabidopsis* E2Fa and DPa transcription factors. Applicants also submit that the polynucleotide is repressed in E2Fa/DPa plants. (reply pages 9-10)

Claims 14 and 48 do not require introducing and expressing a polynucleotide having a sequence of the claims into a plant or a plant cell. Claims 14 and 48 also do not require that a polynucleotide as shown in SEQ ID NO:1835 be over-expressed. Claim 14 is directed to a transgenic plant comprising an isolated nucleic acid sequence which is at least 95% identical to SEQ ID NO:1835. Claim 48 is directed to a transgenic plant comprising an isolated nucleic acid sequence which is at least 95% identical to a sequence encoding SEQ ID NO: 1836. The

Art Unit: 1638

transgenic plants taught by De Veylder L. et al. inherently comprise a nucleic acid sequence which is at least 95% identical to SEQ ID NO:1835 or which is at least 95% identical to a sequence encoding SEQ ID NO:1836, because the transgenic plants are *Arabidopsis thaliana* plants, and SEQ ID NOs:1835 and SEQ ID NO:1836 are obtained from *Arabidopsis thaliana* (sequence listing). The endogenous *Arabidopsis thaliana* nucleotide and amino acid sequences are the same whether they have been isolated or not. Accordingly, De Veylder L. et al. anticipate claims 14 and 48.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1638

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC